Orelle Corporation Limited

JUN 6 2013

510(k) Summary K121902

Submitter: Orelle Corporation Ltd
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Contact: Patricia Coombes
Chief Executive Officer

Summary Prepared: May 24, 2013

Trade Name: NatraTone®

Regulation Name: Perineometer

Classification Regulation: 21 CFR 884.1425
Class II Device

Product Code: 85 HIR

Predicate Device: K021115 – The Naissance Holdings, LLC 'GyneFlex Perineometer'

Device Description:

NatraTone® is a pelvic floor muscle exerciser. It is a single, reusable device that comes into contact with the vaginal mucosal membrane for a limited (<24 hours) duration per each use. The device is 3.25 inches in length, 1.35 inch in width at its bulbous base end and weighs 1 once or 28 grams. The registered trade name 'NatraTone' is embedded in the thumb-hold area of the device. The device is fully inserted to sit low in the vagina in contact with the perineal muscles.

Indications for Use:

The NatraTone® is indicated for the strengthening of the perineal pelvic floor muscles by providing resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, Urinary Incontinence in Women.

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Predicate Device Comparison:

Feature	NatraTone®	GyneFlex (K021115)
Intended Use	Treatment of urinary incontinence	Treatment of urinary incontinence
Design	Symmetrically S-shaped	V-shaped
Mechanism of action	Strengthen the perineal pelvic floor muscles by offering resistance to an individual's voluntary contractions	Strengthen the perineal pelvic floor muscles by offering resistance to an individual's voluntary contractions
Material	Molded medical grade polycarbonate	Molded medical grade plastic polymer
Color	Natural color	Multiple color
Sterilization	Clean, but not sterile	Clean, but not sterile
Prescription	Not required	Not required
Single Patient Device	Yes	Yes
Anatomical Sites	Intra-vaginal	Intra-vaginal
Reusability	Yes	Yes
Duration of Use	Transient	Transient
Instructions	Instructions Manual for patient home use	Instructions Manual for patient home use
Regular Visits to Medical Service Provider	Not required	Not required
Maintenance	Clean with soap and water; towel dry	Clean with soap and water; towel dry
Packaging	Training Aid, Carry Case, Sealable plastic bag for Carry Case, and Instructional Manual in cardboard box	Training Aid and Manual in cardboard box

Material Safety

NatraToner is manufactured with Lexan resin HP4-1H111 that is used in 510(k)-cleared Kolpexin Sphere (K032664). The manufacturing process is identical and there are no additional materials, additives or colorants added to the NatraToner during the manufacturing process or at any other time.

Conclusion

The information in this 510(k) demonstrates that the subject Orelle Corporation NatraTone® is substantially equivalent to the existing GyneFlex device (K021115) with respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 6, 2013

Orelle Corporation Ltd.
% Ms. Patricia Coombes
CEO
7 Highland Drive, Ste. 704
SEATTLE WA 98109

Re: K121902
Trade/Device Name: NatraTone®
Regulation Number: 21 CFR§ 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: May 24, 2013
Received: May 29, 2013

Dear Ms. Coombes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K121902

Device Name: NatraTone®

Indications for Use:

NatraTone® is indicated for the strengthening of the perineal pelvic floor muscles by providing resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, Urinary Incontinence in women.

Prescription Use: _____ AND/OR Over-The-Counter Use: √

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121902